UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,307	09/18/2003	Bassil I. Dahiyat	67461-5041-US06	6927

67374 7590 05/18/2007

MORGAN, LEWIS & BOCKIUS, LLP
ONE MARKET SPEAR STREET TOWER
SAN FRANCISCO, CA 94105

EXAMINER	
DEJONG, ERIC S	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,307	DAHIYAT ET AL.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Claim 6 has been canceled. Claims 1-5 and 7-26 are under examination.

Several unsuccessful attempts were made to contact applicants representative, Robin Silva, on April 23 and 25 and May 1 of 2005 regarding permission for an examiner's amendment and to request the filing of terminal disclaimers in order to advance the instant application to allowance.

Claim Objections

The objection to claims 2-5 as being of improper dependent form is withdrawn in view of amendments made to the instant claims.

Claim Rejections - 35 USC § 101

The rejection of claims 1 and 7-26 under 35 USC § 101 as being drawn to nonstatutory subject matter is withdrawn in view of amendments made to the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Claims 1-5 and 7-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-8 of U.S. Patent No. 6,403,312. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are narrowly drawn to a method for generating a secondary library of protein sequences of a target protein comprising providing coordinated of a target protein, utilizing a force field calculation to generate a primary library of variant proteins, generating a probability distribution, combining a plurality of amino acid residues from said probability distribution to generate a second library and synthesizing a plurality of sequence from said second library, whereas the claims of U.S. Patent No. 6,403,312 are broadly drawn to a method of generating a secondary library of scaffold protein variants comprising providing a first library of protein variants, generating a probability distribution, and synthesizing a plurality of secondary protein variants. However, while the claims of U.S. Patent No. 6,403,312 are generic with regards to utilizing a force field calculation to generate a primary library of variant proteins, the disclosure of U.S. Patent No. 6,403,312 sets forth preferred embodiments of the invention that relies on utilizing a force field calculation to generate a protein structures contained in a primary library (see especially U.S. Patent No. 6,403,312, col. 7, line 26 through col. 9, line 16).

Claims 1-5 and 7-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36-41 of copending Application No. 09/782,004. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the instant claims are narrowly drawn to a method for generating a secondary library of protein sequences of a target protein comprising providing coordinated of a target protein, utilizing a force field calculation to generate a primary library of variant proteins, generating a probability distribution, combining a plurality of amino acid residues from said probability distribution to generate a second library and synthesizing a plurality of sequence from said second library, whereas the claims of copending Application No. 09/782,004 are drawn to a method of generating at least one non-naturally occurring variant protein comprising providing coordinated of a target protein, identifying a list of variable residue positions, applying a force field calculation to generate a primary library of variant proteins, recombining non-variable and variable residue positions to generate a second library and synthesizing a plurality of sequence from said second library. However, while the claims of copending Application No. 09/782,004 recite recombining non-variable and variable residue positions, which is generic to the instantly claims that recite the use of a probability distribution, the disclosure of copending Application No. 09/782,004 and prosecution history demonstrates that said copending claims encompass the use of a probability distribution of amino acids in the generation a secondary library of protein variants (see the specification of copending Application No. 09/782,004, page 28 line 24 through page 30, line 6 and applicants responses and claim sets filed on 06/02/2004 and 08/09/2004 in said application).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is acknowledged that the instant application is a divisional of copending application 09/782,004. However, regarding when prohibition of a double patenting rejection under 35 USC § 121 does not apply, MPEP 804.01(B) states:

> "The claims of the different applications or patents are not consonant with the restriction requirement made by the examiner, since the claims have been changed in material respects from the claims at the time the requirement was made. For example, the divisional application filed includes additional claims not consonant in scope to the original claims subject to restriction in the parent. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 19 USPQ2d 1241 (Fed. Cir. 1991) and Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 16 USPQ2d 1436 (Fed. Cir. 1990). In order for consonance to exist, the line of demarcation between the independent and distinct inventions identified by the examiner in the requirement for restriction must be maintained. 916 F.2d at 688, 16 USPQ2d at 1440."

In copending Application No. 09/782,004, applicants elected the invention of Group I as set forth in the restriction requirement mailed 06/30/2003. Following this election, applicants introduced amended claims that introduced the subject matter of the non-elected invention of Group VI, drawn to methods for generating a secondary library by probability distribution, in responses filed 06/02/2004 and 08/09/2004 which were subsequently examined on their merits. Therefore, the claims of copending Application No. 09/782,004 are not consonant with the original restriction requirement since the claims have been changed in material respects from the claims at the time the original restriction requirement was made.

Claims 1-5 and 7-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52-69 of copending Application No. 09/927,790. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are narrowly

drawn to a method for generating a secondary library of protein sequences of a target protein comprising providing coordinated of a target protein, utilizing a force field calculation to generate a primary library of variant proteins, generating a probability distribution, combining a plurality of amino acid residues from said probability distribution to generate a second library and synthesizing a plurality of sequence from said second library, whereas the claims of copending Application No. 09/927,790 are drawn to a generic method of generating at least one non-naturally occurring variant protein comprising providing coordinated of a target protein, identifying a list of variable residue positions, applying at least one scoring function to generate a primary library of variant proteins, recombining non-variable and variable residue positions to generate a second library and synthesizing a plurality of sequence from said second library. However, while the claims of copending Application No. 09/927,790 recite recombining non-variable and variable residue positions to generate a secondary library, which is generic to the instantly claims that recite the use of a probability distribution, the disclosure of copending Application No. 09/927,790 teaches recombining step encompass the use of a probability distribution of amino acids in the generation a secondary library of protein variants (see the specification of copending Application No. 09/927,790, page 28 line 24 through page 30, line 6).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shukla Ram can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Examiner
Art Unit 1631